Introduction to Risk Management
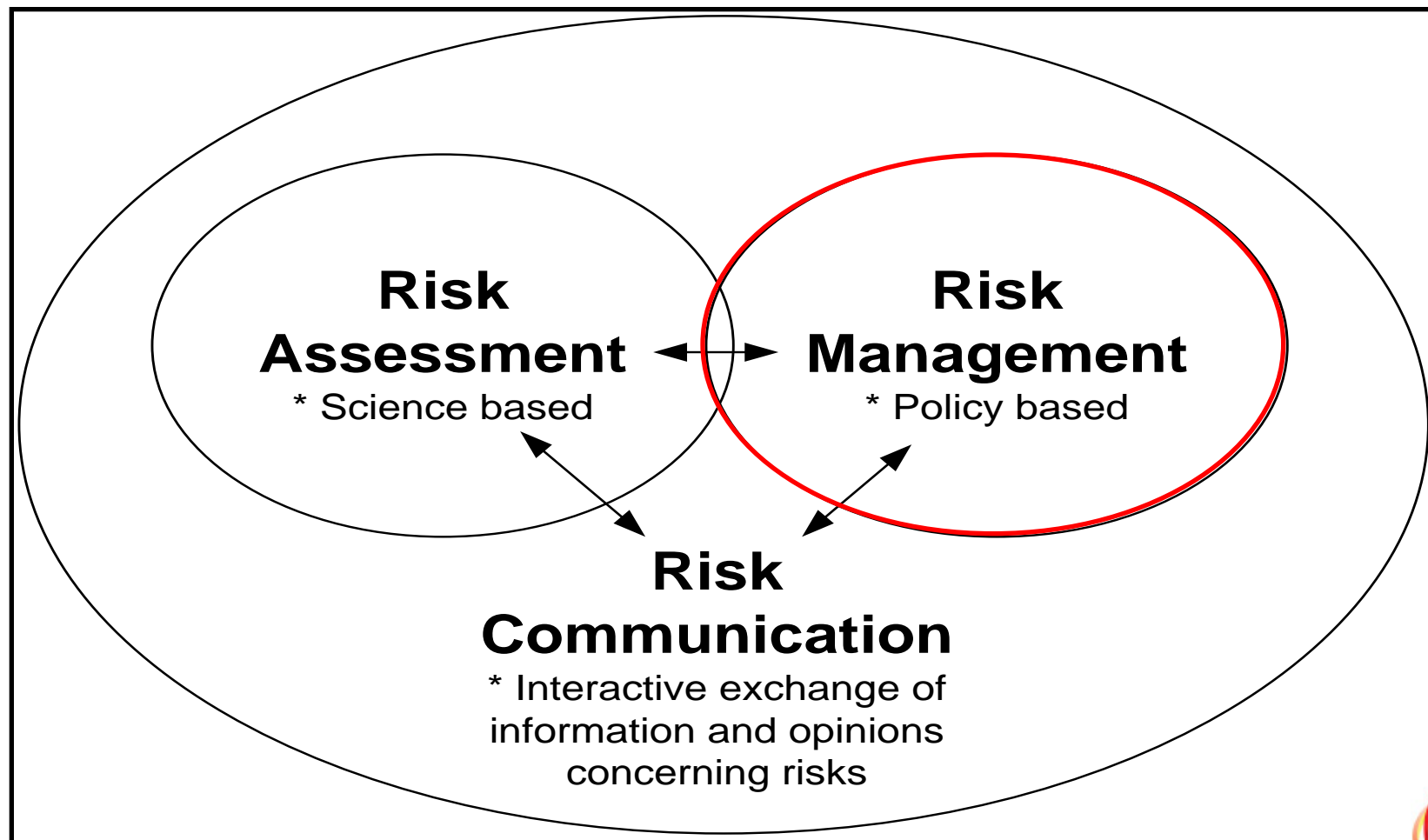
Risk Analysis Framework

Risk Assessment
* Science based

Risk Management
* Policy based

Risk Communication
* Interactive exchange of information and opinions concerning risks

Risk Management

- Process by which governments or businesses use evaluations of risks of adverse events to develop and implement systems that prevent or minimize the occurrence or severity of hazards that have been determine to have an unacceptably high level of risk

- Used as a formal process for making informed decisions related to ensuring that adequate controls are implemented to ensure the "safety" of consumers, businesses, and organizations

Current Approaches

- Various sectors of the food industry work with different combinations of three types of food safety systems
  - Good Hygienic Practice-based: Based on standard practices used universally by food operators; usually qualitative
  - Hazards-based: Hazard-based system tailored to individual facilities; qualitative or semi-quantitative
  - Risk-based: HACCP system based on risk assessments and the application of risk management principles and metrics; quantitative

Who is a Risk Manager?

- Who is designated as a "risk manager" has been controversial
  - Prospects.com:
    - Risk managers advise organizations on any potential risks to the profitability or existence of the company
    - They identify and assess threats, put plans in place for if things go wrong and decide how to avoid, reduce or transfer risks
  - Codex Alimentarius:
    - A national or international governmental organization with responsibility for risk management

- Who are the food safety risk managers in Zambia?

Evolution of Food Safety Risk Management Systems
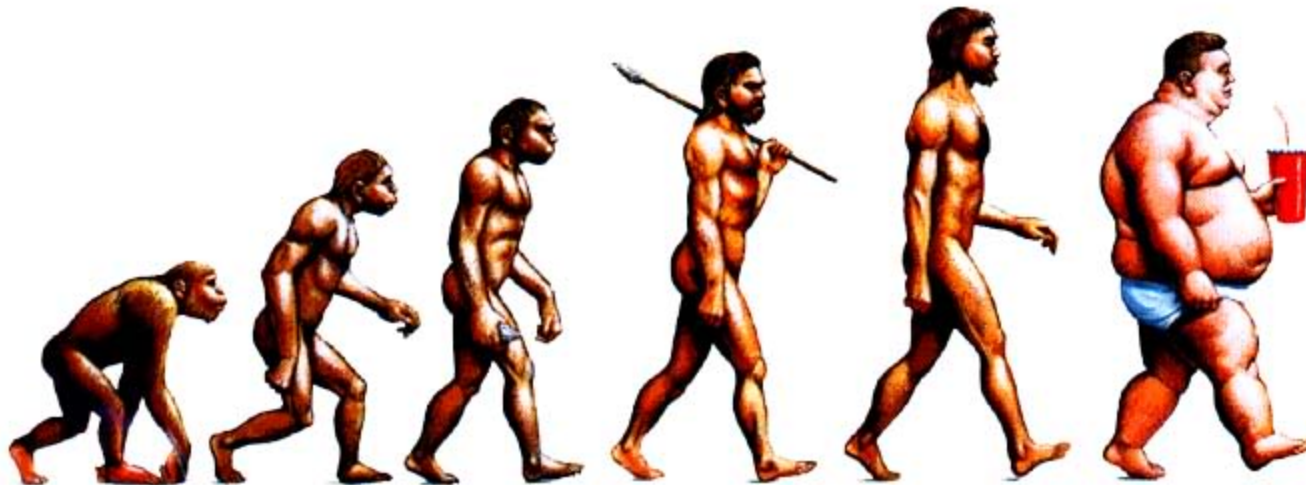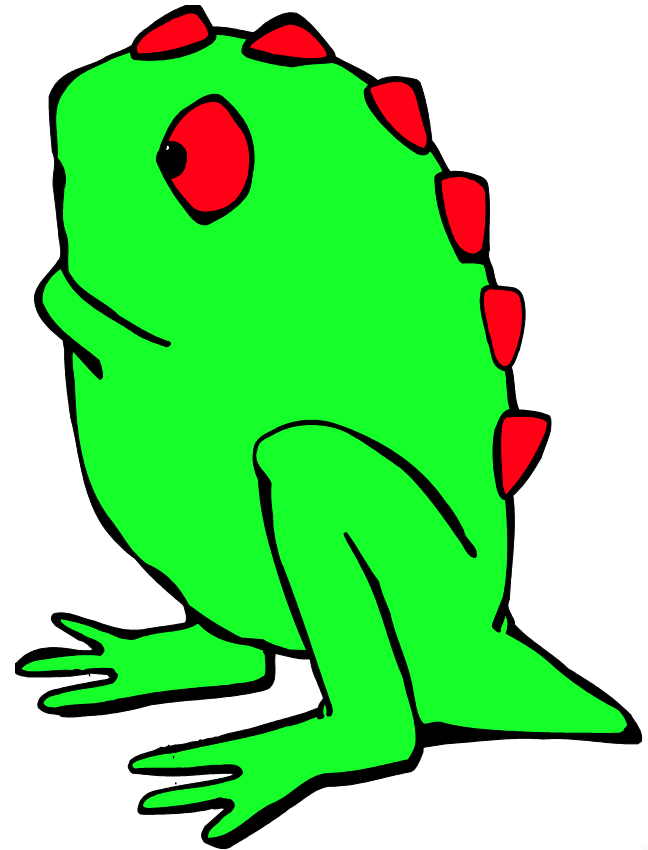
Evolving Food Control Frameworks

- Traditionally, the degree of control of food safety concerns (other than food additives) have been based on the concept of achieving control "As Low As Reasonably Achievable" (ALARA)

Evolving Food Control Frameworks

- ALARA-based systems are often controversial

- "Reasonable," like beauty, is in the eyes of the beholder

Evolving Food Control Frameworks

- Disagreements arise when:
  - an industry is very heterogeneous in relation to technological capabilities or resources
  - the technological capabilities or approaches of two countries differ greatly
  - there is no clear cut means of controlling a hazard
  - Expectations of a country's consumers and/or its public health community differ from industry's or an exporting country

Evolving Food Control Frameworks

- Worldwide we have seen an evolution in how food safety hazards are managed within a risk analysis framework
  - 1850 – 1960: Command and Control ("Father Knows Best") System
  - 1950 – 1990: GHPs and Early HACCP
  - 1980 – Present: Benchmarked HACCP
 - 1995 – Present: Public health goal-based risk management

Evolving Food Control Frameworks

- In the past two decades have seen a transition from hazards-based to risk-based food safety management systems
  - Provide transparent public health-based, risk-based decisions
  - Optimize control of competing risks
  - Deal effectively with the diversity of the population and the marketplace
  - Deal with the international interdependence of the marketplace
- Accelerated by advances in risk-based decision-making tools and increased scientific knowledge

Food Safety Policy (Risk Management) Concepts
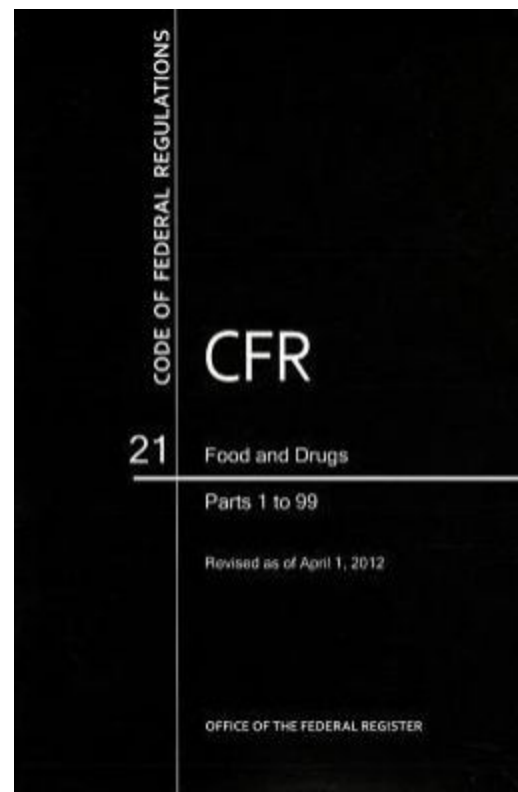
Food Safety Policy Is Based on Risk Management
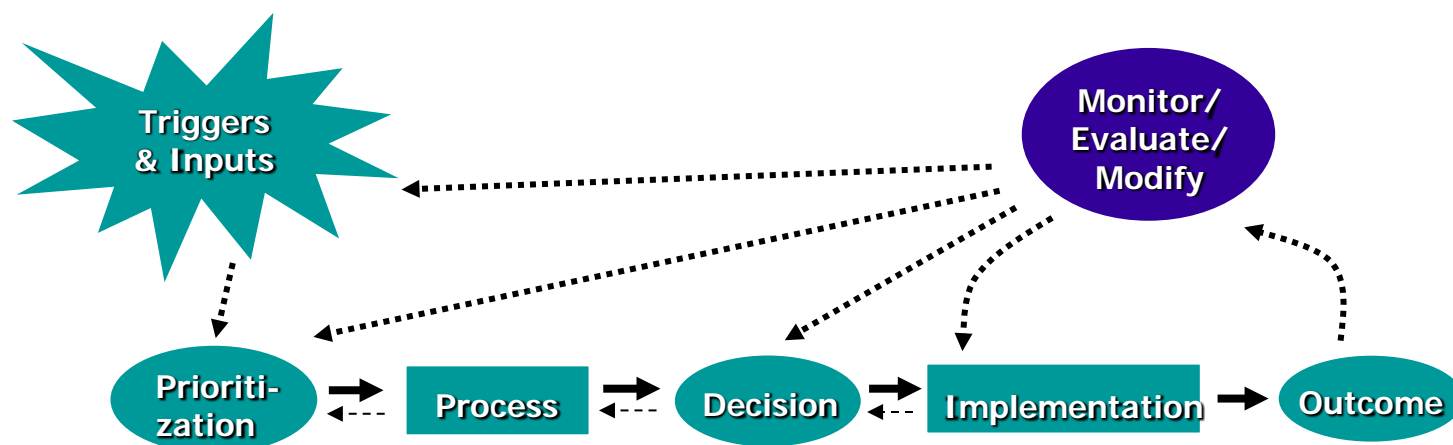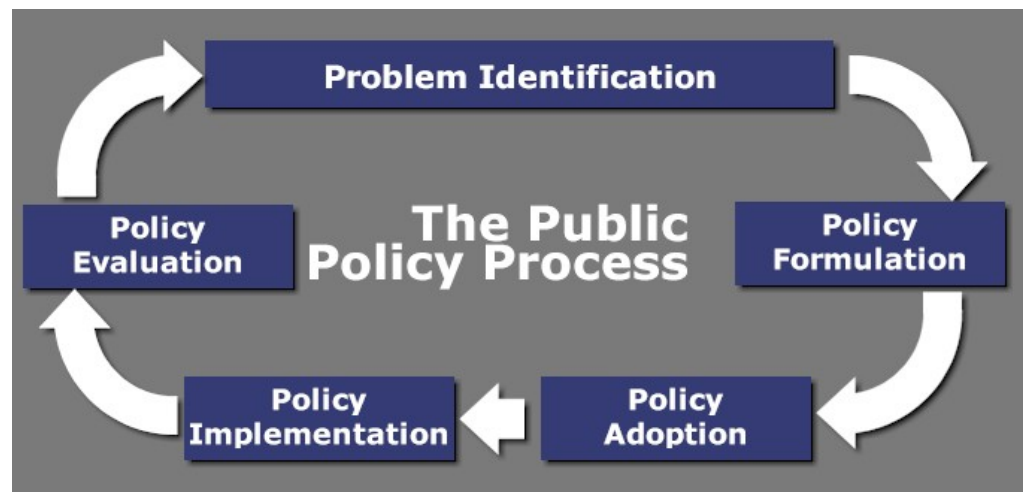
Public Health Policy and Risk Management

- Public health policy and food safety risk management are interconnected

- Understanding food safety risk management requires a familiarity with basic concepts in food safety policy

- While food safety risk assessors have devoted a substantial amount of time "conceptualizing" what they do, it is less so with food safety risk managers

Food Policy Concepts

- The responsibility for producing and marketing safe foods lies with the industry
- The role of government regulatory agencies is:
  - Establish the stringency and equivalence of food safety systems
  - Ensure that industry is meeting its responsibilities
- Roles often confused in the mind of the public

Food Policy Concepts

- Food policy/risk management decisions are "societal" decisions

- Inherently complex because they must balance

  - Sound science

  - Existing food safety laws and policies

  - Economic realities of food availability

  - The diverse interests of stakeholder

Food Policy Concepts

- Stringency of a food safety system is a relative attribute

- Established by setting critical limits or performance criteria such as microbiological criteria or maximum daily intake values

Stringency: Picking a Level

- Stringency for a specific hazard/food pair is dependent on
  - Probability of occurrence
  - Severity of hazard
  - Population affected
  - Extent of consumption
  - Avoidability
  - Potential for control
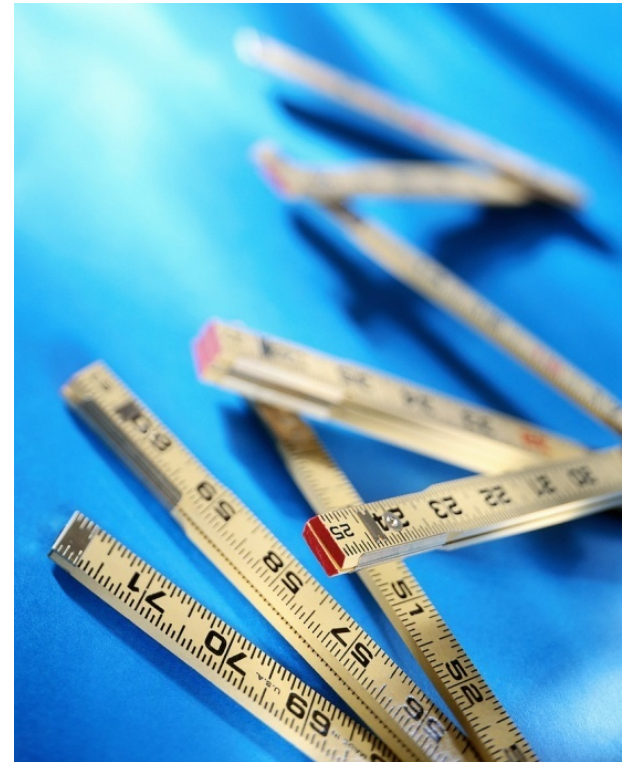 - Alternative foods
  - Others

Food Policy Concepts

- The degree of "regulatory control" placed on a **hazard-food** pair should be a function of the risk to public health

Food Policy Concepts

- One cannot regulate what they cannot readily measure and document

- Establishing the stringency of a food control system is meaningless unless it can be verified

Food Policy Concepts

- "Level Playing Field"
  - Fairness concept: All companies play by the same set of rules
  - Food safety requirements have the potential for hindering some companies from competing in the marketplace
  - If crafted well, government regulations provide such fairness

Equivalence

- Food safety systems that provide a similar degree of stringency should be considered equivalent

- Maximizes
  - Flexibility
  - Fairness
  - Innovation
  - Risk-based decisions
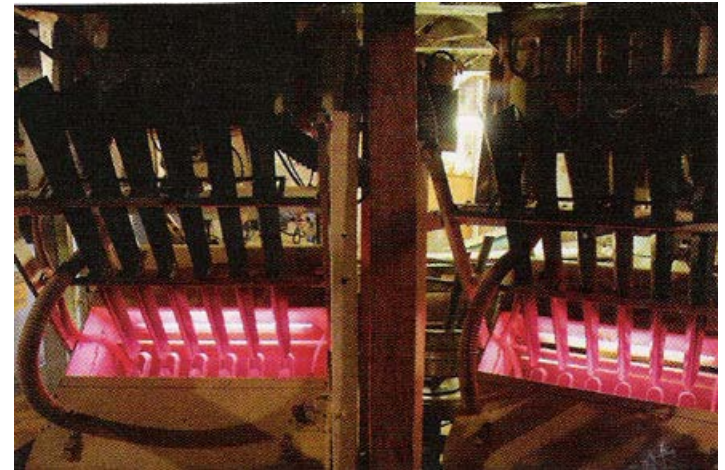
Proportionality

- Foods with similar risks should have similar levels of regulatory control

Uncertainty and Variability

- Managing uncertainty is an integral part of industry and regulatory decisions

  – Integral to informed decisions

  – Must consider variability and uncertainty of foods, hazards, processes, and consumers

  – Use "safety margins" to offset uncertainty

  – Extent of precaution should be proportional to the magnitude of the risk (probability + severity) and its uncertainty

Food Policy Concepts

- Food safety policies generally work best when their development and implementation are as "transparent" as possible

- One of outcomes of effective risk communications is enhanced transparency

Food Safety Policy

- "Food law" is a "binary" system
  - Must establish a consistent way of deciding what foods in the marketplace are or are not acceptable (i.e., safe/not safe; acceptable/unacceptable)
  - Cannot be arbitrary or capricious

- Compliance to a "food law" should be verifiable with the stringency for similar risks being the same

- "Food law" based on performance fosters innovation but requires higher level of sophistication
  - Default requirements as "safe harbor"

Science-Based

- Application of scientific knowledge within a framework of laws that defines the risk management options (and their limits) that are available to regulatory agencies and industry

Food Safety Policy

- Food safety laws and policies are typically written vaguely

- Food safety policies are interpreted and applied in relation to

  - Existing statutes

  - Past practices

  - Case law

  - Consistency

  - Science

- Cannot go beyond authority provided by statutes

Risk Management within the Food Industry

Food Safety Systems

- Currently, the combination of GMPs and HACCP is the gold standard worldwide for the management of food safety risks

Good Hygienic Practices

- Primary means of ensuring food safety is through GHPs
- Group of "best practices" that should be incorporated into the production, processing, distribution, and marketing, and preparation of foods
- Subdivided based on sectors along the food chain
  - Food Primary Production: Good Agricultural Practices (GAPs)
  - Food Manufacturing: Good Manufacturing Practices (GMPs)
  - Food Service: Food Code

What Happens When GHPs Are Not Enough???

- Historically, the development and implementation of GHPs <u>greatly reduced </u>the incidence of foodborne disease

- However, adoption of GHPs <u>did not eliminate </u>foodborne disease

- The remaining failures were often associated with specific activities that experienced periodic failures due to:
  - Treatments that are insufficient to deal with the variability of foods
  - Reliability of personnel and equipment
  - Failure to identify specific hazards

- Led to development and adoption of HACCP

HACCP as a Food Safety System

- First attempt at taking a "systems approach" to food safety, i.e., design safety into manufacturing

- Semi-quantitative risk management system based on a largely qualitative "hazard" (risk) assessment

- Focus is on individual food manufacturing facilities but benefits from consideration of other sectors

Failure Mode and Effect Analysis

- Based on FMEA
  - Identify steps in a system that are likely to fail
  - Determine the consequences of the failures
  - Modify the system so that priority failures:
    - Happen less often, or
    - Have less of a consequence

HACCP Concepts

- "…the HACCP team conducts a hazard analysis and identifies appropriate control measures. The purpose of the hazard analysis is to develop a list of hazards which are <u>of such significance that they are reasonably likely to cause injury or illness if not effectively controlled</u>."

- "Hazards that are not reasonably likely to occur would not require further consideration within a HACCP plan."

NACMCF, 1997

Significant Hazards

- Critical determinant of the potential effectiveness of a HACCP program

- Substantial portion of food industry considers that a hazard analysis is something distinctly different from a risk assessment

- Needs to assess two aspects of a food safety system
  - Risk of key failures in operations – Compliance Risks
  - Remaining risks when system under control - Residual Risks

HACCP as a Risk Management System

- Risk-based decision criteria in a HACCP system are set by
  - Hazards considered significant
  - Critical Control Points identified
  - Critical Limits established
  - Frequency and sensitivity of the CCP monitoring activities
  - Frequency and sensitivity of HACCP verification programs

HACCP as a Risk Management System

- All of the attributes depend on answering the question:

  - "How much is enough???"

- Too little and increase public health risks

- Too much and reduce quality and increase cost